



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0651; FRL-8623-01-OCSP]

Zeta-Cypermethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of zeta-cypermethrin in or on multiple commodities that are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0651, is available online at <http://www.regulations.gov> or in-person at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to

provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in

40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0651 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0651, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of April 15, 2020 (85 FR 20910) (FRL-10006-54), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8790) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested EPA to establish

tolerances in 40 CFR part 180 for residues of zeta-cypermethrin (S-cyano(3-phenoxyphenyl) methyl (\pm))(cis-trans 3-(2,2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate), including its metabolites and degradates, measuring only total cypermethrin, cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate, in or on 116 separate commodities and to remove 52 established commodities upon establishment of the new commodities. Due to the length of the list of commodities, please refer to the Notice of Filing referenced above for a complete list of commodities to be established and removed. That document referenced a summary of the petition prepared by FMC, the registrant, which is available in the docket, <http://www.regulations.gov>. A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing some tolerances at different levels than were petitioned for and is also modifying some of the commodity definitions to be consistent with Agency nomenclature. The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA

section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for zeta-cypermethrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with zeta-cypermethrin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Type II pyrethroids, such as the cypermethrins (cypermethrin, zeta-cypermethrin, and alpha-cypermethrin), contain an alpha-cyano moiety, and in rats produce a syndrome that includes pawing, burrowing, salivation, hypothermia, and coarse tremors leading to choreoathetosis. The adverse outcome pathway (AOP) shared by pyrethroids involves the ability to interact with voltage-gated sodium channels (VGSCs) in the central and peripheral nervous system, leading to changes in neuron firing and, ultimately, neurotoxicity.

The toxicology database for the cypermethrins is considered complete with respect to guideline toxicity studies. While each active ingredient does not have its own complete database, studies have been bridged across the three chemicals and together are considered adequate for human health risk assessment. When evaluated together, the toxicity database for the cypermethrins can be used to characterize the overall suite of effects associated with cypermethrin exposure, including potential developmental and reproductive toxicity, immunotoxicity, and neurotoxicity.

The cypermethrins affect the nervous system, and neurotoxicity is the most sensitive effect observed throughout the toxicology database. Effects (clinical signs of neurotoxicity) were seen for all three compounds across species, sexes, and routes of administration. The endpoints

and points of departure (PODs) selected for risk assessment are based on neurotoxicity and are protective of all toxic effects observed in the database.

There was no evidence of increased quantitative or qualitative susceptibility in the available rat and rabbit developmental toxicity studies and rat two-generation reproductive studies with the cypermethrins. A developmental neurotoxicity (DNT) study with zeta-cypermethrin indicated increased sensitivity in the offspring, based on body weight changes in pups in the absence of treatment-related effects in maternal animals at the highest dose tested. However, there is a clear NOAEL for effects seen in pups, and the doses and endpoints selected for risk assessment are protective of the susceptibility.

For pyrethroid chemicals, the pharmacokinetics indicate that the onset of neurotoxicity is rapid, with the time to peak effect for neurobehavioral effects occurring within hours. This is followed by rapid metabolism and elimination that does not result in accumulation. For the cypermethrins, the points of departure (PODs) for clinical signs after single or repeated exposure are comparable across durations of exposure. Thus, consistent with this class of compounds, neurotoxicity is not considered to progress with repeated exposure. Therefore, repeated dosing is essentially a series of acute exposures. As there is no apparent increase in hazard from repeated/chronic exposures to cypermethrins, the acute exposure assessment is protective of chronic exposures. The totality of the information suggests that only single day risk assessments need to be conducted for the cypermethrins.

Cypermethrin is classified as a Group C "Possible human carcinogen," based on an increased incidence of benign lung adenomas and adenomas plus carcinomas combined in females in a mouse carcinogenicity study. No tumors were seen in cypermethrin cancer studies in rats or in a cancer study in mice with alpha-cypermethrin. The Agency has determined that quantification of cancer risk using a non-linear approach (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to the cypermethrins. While the Agency would typically use a chronic population adjusted dose

(cPAD) to protect for cancer concerns, use of the acute population adjusted dose (aPAD) is considered protective because increasing toxicity with increasing duration of exposure is not demonstrated for the cypermethrins. The NOAEL in the mouse cancer study is 57 mg/kg/day and tumors were seen at 229 mg/kg/day. The acute point of departure (POD) of 7.16 mg/kg/day selected for risk assessment is 32-fold lower than the dose that induced lung tumors in mice. Only the mouse study with cypermethrin resulted in tumor formation: no evidence of carcinogenicity was observed in cancer studies in rats with cypermethrin or mice with alpha-cypermethrin.

Specific information on the studies received and the nature of the adverse effects caused by zeta-cypermethrin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document titled “Zeta-Cypermethrin, Human Health Risk Assessment for a Proposed Use on Basil and Various Crop Group Expansions and Conversions” (hereinafter “Zeta-Cypermethrin Human Health Risk Assessment”) on pages 45-51 in docket ID number EPA-HQ-OPP-2019-0651.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to

some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide>.

A summary of the toxicological endpoints for zeta-cypermethrin used for human risk assessment can be found in the Zeta-Cypermethrin Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to zeta-cypermethrin, EPA considered exposure under the petitioned-for tolerances as well as all existing tolerances for the cypermethrins in 40 CFR 180.418. EPA assessed dietary exposures from zeta-cypermethrin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

In conducting the acute dietary exposure assessment, EPA used the 2003-2008 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute dietary exposure assessment is a refined probabilistic assessment based on tolerance level residues for most commodities and Pesticide Data Program (PDP) monitoring data for the commodities that make the most significant contribution to dietary risk. Estimates of the maximum percent crop treated were used for the same commodities for which PDP data were used and for one commodity for which the tolerance was used. Additional information on the assumptions used in the acute assessment can be found on pages 35-36 in the Zeta-Cypermethrin Human Health Risk Assessment.

ii. *Chronic exposure.* A chronic dietary risk assessment is not required for zeta-

cypermethrin because repeated exposure does not result in a POD lower than that resulting from acute exposure. Therefore, the acute dietary risk assessment is protective of chronic dietary risk. However, EPA performed a chronic dietary exposure assessment for use in the aggregate assessment, since there are residential exposures for zeta-cypermethrin that need to be aggregated with background exposure from dietary sources. In the aggregate human health risk assessment, the average or chronic exposure estimates are combined with the appropriate residential exposure estimates and compared to the POD for zeta-cypermethrin.

The chronic dietary exposure assessment is a highly refined assessment based on Pesticide Data Program (PDP) monitoring data for most commodities. Tolerance level residues were used for a small number of commodities including fresh and dried basil; however, these commodities are not highly consumed and, therefore, they make a negligible contribution to the dietary risk. Refining the residue estimates for these commodities would have an insignificant effect on exposure estimates. As with the acute assessment, conservative default processing factors were generally used for the processed commodities for which they were available. The Agency made the conservative assumption that 100% of all commodities would be treated. When monitoring data were used, average residues were calculated by incorporating $\frac{1}{2}$ limit of detection (LOD) values for all non-detects. No zeros were used to calculate the average residues. The cypermethrins have food handling establishment (FHE) uses that need to be accounted for in the chronic dietary exposure assessment. For these uses, EPA used a residue value of one-half the tolerance. BEAD provided an estimate of the probability that a food item a person consumes contains residues as a result of treatment in an FHE at some point with any pesticide. It is not specific to the cypermethrins. This estimate is 4.65%. In the chronic assessment, this value was used for the same commodities as the ones with the FHE residue value (0.025 ppm). In cases where the total anticipated residue from the FHE use exceeded the total anticipated residue from the agricultural use, the FHE anticipated residue was used.

iii. *Cancer*. Cypermethrin is classified as a Group C “Possible human carcinogen,” based

on an increased incidence of benign lung adenomas and adenomas plus carcinomas combined in females in a mouse carcinogenicity study on cypermethrin. The Agency has determined that quantification of risk using a non-linear approach (i.e., aPAD or aRfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to the cypermethrins.

iv. Anticipated residue and PCT information. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the acute assessment, the following PCT assumptions were made:

Cypermethrin

The following maximum percent crop treated estimates were used in the acute dietary risk assessment for the following crops that are currently registered for cypermethrin: lettuce, head: 5%; lettuce, leaf: 5%; broccoli: 10%; cabbage: 10%; cauliflower: 10%.

Zeta-Cypermethrin

The following maximum percent crop treated estimates were used in the acute dietary risk assessment for the following crops that are currently registered for zeta- cypermethrin: lettuce, head: 75%; lettuce, leaf: 75%; spinach: 55%; celery: 60%; broccoli: 30%; cabbage: 45%; cauliflower: 25%; bean, green: 20%; tomato, puree: 20%; orange, juice: 55%; grapefruit, juice: 65%; peach: 10%; grape: 5%; rice: 15%; sugarcane: 2.5%.

Alpha-Cypermethrin

The following maximum percent crop treated estimates were used in the acute dietary risk assessment for the following crops that are currently registered for cypermethrin: lettuce, head: 20%; lettuce, leaf: 20%; spinach: 2.5%; celery: 2.5%; broccoli: 2.5%; cabbage: 2.5%; cauliflower: 2.5%; bean, green: 2.5%; tomato, puree: 2.5%; orange, juice: 2.5%; grapefruit, juice: 2.5%; rice: 85%.

In the chronic assessment, the Agency made the conservative assumption of 100% crop treated for all commodities with established tolerances. However, PCT was effectively incorporated into the assessment through the use of monitoring data for some commodities, which reflect the PCT for commodities in commerce. For the FHE uses, EPA incorporated an estimate of the probability that a food item a person consumes contains residues as a result of treatment in an FHE at some point with any pesticide. This estimate is 4.65%, which is not specific to the cypermethrins. In the chronic assessment, EPA used this value for all commodities that do not have established tolerances. EPA also used this value when the total anticipated residue for a commodity was higher for the FHE use than it was for the agricultural use.

In most cases, EPA uses available data from United States Department of

Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which zeta-cypermethrin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water

exposure models in the dietary exposure analysis and risk assessment for zeta-cypermethrin in drinking water. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Surface Water Concentration Calculator (SWCC) and the Pesticide Root Zone Model for Groundwater (PRZM-GW), for the acute dietary risk assessment, EPA used an estimated drinking water concentration (EDWC) of 3.5 ppb in the DEEM-FCID Model. For the chronic exposure assessment (used to determine background exposure from food and drinking water for the purpose of aggregate risk assessment), EPA used a value of 0.035 ppb for both direct and indirect water. The groundwater estimate of 0.0036 ppb was much lower than surface water residues; therefore, the Agency used the surface water EDWCs in the assessments. The use of the surface water values in the dietary exposure assessment is protective of potential exposure through groundwater sources of drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). The cypermethrins are registered for a variety of non-agricultural purposes including recreational sites (i.e., golf courses, athletic fields); indoor residential/commercial/industrial sites/structural/perimeter and lawn uses; gardens and trees; as well as mosquito adulticide, termiticide, and pet uses. The current action does not add any new uses with residential exposures.

For assessing aggregate exposure to adults, the Agency used exposures from the inhalation handler scenario from applying cypermethrin with a sprinkler can to home gardens. For assessing aggregate exposure to children, the Agency used exposures to children 1 to <2 years old (dermal and incidental oral) from post-application exposure to pets treated with the pet medallion/tag formulated with zeta-cypermethrin.

The PODs for the oral and dermal routes are based on the same effects: therefore, for

children, the oral and dermal routes can be combined. Since the levels of concern for incidental oral risk and inhalation risk are different (100 and 30), the aggregate risk index (ARI) approach was used to calculate aggregate exposure and risk for adults. An $ARI \geq 1$ is not of concern.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

The Agency has determined that the pyrethroids and pyrethrins share a common mechanism of toxicity <http://www.regulations.gov>; EPA-HQ-OPP-2008-0489-0006. As explained in that document, the members of this group share the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. In 2011, after establishing a common mechanism grouping for the pyrethroids and pyrethrins, the Agency conducted a cumulative risk assessment (CRA) which is available at <http://www.regulations.gov>; EPA-HQ-OPP-2011-0746. In that document, the Agency concluded that cumulative exposures to pyrethroids (based on pesticidal uses registered at the time the assessment was conducted) did not present risks of concern. For information regarding EPA's efforts to evaluate the risk of exposure to this class of chemicals, refer to <https://www.epa.gov/ingredients-used-pesticide-products/pyrethrins-and-pyrethroids>.

Since the 2011 CRA, for each new pyrethroid and pyrethrin use, the Agency has conducted a screen to evaluate any potential impacts on the CRA prior to those uses being granted. The most recent screen, which takes into account the previous uses and the new use on basil, demonstrates that the new uses will not significantly impact the cumulative assessment

because dietary exposures comprise only a minor contribution to the total pyrethroid exposure.

Therefore, there are no cumulative risks of concern for the pyrethroids and pyrethrins.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased qualitative or quantitative susceptibility was noted in the developmental toxicity or reproduction studies for the cypermethrins. However, quantitative susceptibility was seen in the rat developmental neurotoxicity (DNT) study with zeta-cypermethrin with an increased sensitivity in the offspring based on body weight changes in pups (5-10%) in the absence of adverse, treatment-related effects in maternal animals. The results from the DNT study are very similar to results observed in the reproduction studies where body weight (BW) changes (decreased BW gain) were seen in maternal and offspring animals at doses similar to those in the DNT study, with no indication of increased susceptibility. Therefore, there is no residual concern for effects observed in the study and a clear developmental NOAEL and LOAEL were identified.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for the cypermethrins is complete.
- ii. Like other pyrethroids, the cypermethrins cause neurotoxicity by interacting with

sodium channels, leading to clinical signs of neurotoxicity. These effects are well characterized and adequately assessed by the available guideline and non-guideline studies. There are no residual uncertainties with regard to evidence of neurotoxicity for the cypermethrins.

iii. No evidence of increased qualitative or quantitative susceptibility was noted in the developmental toxicity or reproduction studies for the cypermethrins. However, quantitative susceptibility was seen in the rat developmental neurotoxicity (DNT) study, but for the reasons discussed in Unit III.D.2, there is no residual concern for effects observed in the study and a clear developmental NOAEL and LOAEL were identified.

iv. There are no residual uncertainties identified in the exposure databases. The dietary exposure assessments account for parent and metabolites of concern. The assessments include percent crop treated assumptions and conservative, default processing factors. Furthermore, conservative, upper-bound assumptions were used to determine exposure through drinking water and residential sources, such that these exposures have not been underestimated.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to zeta-cypermethrin from food and water will utilize 35% of the aPAD for adults 20 to 49 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* A chronic dietary risk assessment is not required for zeta-cypermethrin

because repeated exposure does not result in a POD lower than that resulting from acute exposure. Therefore, the acute dietary risk assessment is protective of chronic dietary risk.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Zeta-cypermethrin is registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to zeta-cypermethrin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 140 for children and an ARI of 4.7 for adults. Because EPA's level of concern for zeta-cypermethrin is an MOE of 100 or below, or an ARI of 1 or below, these MOEs/ARIs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). While there is potential intermediate-term residential exposure, because the single dose and repeat dosing cypermethrin studies show that repeat exposures do not result in lower points of departure, the residential assessments are conducted as a series of acute exposures and the same endpoint is used regardless of duration. Therefore, the short-term aggregate assessment is considered protective of any intermediate-term exposures.

5. *Aggregate cancer risk for U.S. population.* EPA has classified zeta-cypermethrin as a "possible human carcinogen" and determined that a non-linear approach should be used for cancer assessment. As the acute dietary exposure estimates are not of concern, cancer risk is not of concern.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to zeta-cypermethrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate tolerance-enforcement methods are available in *PAM Volume II* for determining residues of zeta-cypermethrin in plant (Method I) and livestock (Method II) commodities. Both methods are gas chromatographic methods with electron-capture detection (GC/ECD). These methods are not stereospecific; therefore, no distinction is made between residues of cypermethrin (all 8 stereoisomers), zeta-cypermethrin (enriched in 4 isomers) and alpha-cypermethrin (enriched in 2 isomers).

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There is no Codex MRL for cypermethrin or the enriched forms, alpha- and zeta-cypermethrin, in/on basil. There are, however, Codex MRLs for numerous commodities contained in the crop groups and subgroups for which tolerances are being established in this rulemaking. EPA is harmonizing the tolerances with Codex MRLs for teff, grain; tomato; the commodities in the fruit, stone group 12-12, fruit, citrus subgroups 10-10A, 10-10B, and 10-10C, and the nut, tree, group 14-12; edible podded beans and peas; and dried beans and peas.

EPA is not harmonizing several U.S. tolerances with corresponding Codex MRLs

because the Codex MRLs are lower than the U.S. tolerances. The available residue data indicate that use under registered U.S. pesticide products would exceed the Codex MRLs and thus harmonizing could result in food being adulterated when following approved label instructions. EPA does not consider the lack of harmonization in these instances to provide a trade barrier to imports since commodities that comply with the Codex MRL could be imported into the United States. The U.S. tolerances that are not being harmonized for this reason are onion, bulb, subgroup 3-07A; onion, green, subgroup 3-07B; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F; rapeseed, subgroup 20A; sunflower, subgroup 20B; cottonseed, subgroup 20C; quinoa, grain; leafy greens subgroup 4-16A; *Brassica*, leafy greens, subgroup 4-16B; vegetable, *Brassica*, head and stem, group 5-16; fruit, pome, group 11-10; and kohlrabi.

In addition, EPA is establishing tolerances for the fruiting vegetable crop group 8-10, which includes tomato, bell pepper, nonbell pepper, eggplant, and okra, at 0.2 ppm because the available representative commodity data support establishing the crop group at 0.2 ppm. While this action harmonizes with the Codex MRL for tomato, it results in tolerance levels for the other commodities in the crop group being different from the Codex MRLs for other commodities in that group since Codex has established different levels for the different commodities. EPA has determined it is appropriate to maintain the crop group based on the representative commodity data supporting the group tolerance. Finally, EPA is not harmonizing tolerances for succulent shelled beans and peas commodities with the Codex MRLs for such commodities because the magnitude of the difference is too great. The current tolerance for the subgroup is 0.1 ppm, versus the Codex MRL of 0.7 ppm. In addition, the U.S. tolerance is currently harmonized with the Canadian MRL of 0.1 ppm for succulent shelled peas.

C. Response to Comments

One comment was received in response to the Notice of Filing. The comment stated in part that the Agency should “deny ir4 rutgers chemical profiteering college from getting a permit.” Although the Agency recognizes that some individuals believe that pesticides should be

banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the zeta-cypermethrin tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

D. Revisions to Petitioned-For Tolerances

Commodity definitions have been corrected to be consistent with Agency nomenclature. Also, EPA is not establishing a tolerance for edible podded pea as requested because the commodity is being removed from the proposed crop group 6-19. Edible podded pea is being removed from proposed crop group 6-19 because it is not referring to any specific pea.

The petitioner requested a tolerance of 0.7 ppm for the individual commodities in the proposed revisions to crop subgroup 6B, succulent shelled pea and bean subgroup. EPA is not revising the level of the individual tolerances because the magnitude of the difference is too great. The current tolerance for the subgroup is 0.1 ppm. In addition, the U.S. tolerance is currently harmonized with the Canadian MRL of 0.1 ppm for succulent shelled peas.

The petitioner requested a tolerance of 0.35 ppm for fruit, citrus, group 10-10. Codex has established MRLs of 0.3 ppm for citrus except pummelo and shaddock, and 0.5 ppm for the pummelo and grapefruits subgroup (including shaddock-like hybrids among other grapefruits). The 0.3 ppm Codex MRL is based on U.S. residue data. As a result, the Agency is establishing a tolerance of 0.3 ppm for the orange subgroup 10-10A and the lemon/lime subgroup 10-10B. The Agency is also establishing a tolerance of 0.5 ppm for the grapefruit subgroup 10-10C to harmonize with the Codex MRL of 0.5 ppm for the pummelo and grapefruits subgroup.

The petitioner requested a tolerance of 0.2 ppm for teff, grain. There is a Codex MRL of 0.3 ppm for Cereal grains except rice, barley, oats, rye, and wheat. The Codex cereal grains crop group includes teff. As a result, EPA is setting the tolerance on teff, grain at 0.3 ppm to

harmonize with Codex.

E. International Trade Considerations

In this rule, EPA is establishing a lower tolerance for zeta-cypermethrin residues in or on the orange subgroup 10-10-A and the lemon/lime subgroup 10-10B than the current tolerance. The current tolerance for the fruit, citrus, group 10 is 0.35 ppm. For the reasons explained in Unit IV.D of this document (i.e. to harmonize with the Codex MRLs), the Agency believes these revised, lower tolerances are appropriate.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of the changes to these tolerances in order to satisfy its obligations under the Agreement. In addition, the SPS Agreement requires that Members provide a "reasonable interval" between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. Accordingly, EPA is establishing an expiration date for the existing tolerance to allow this tolerance to remain in effect for a period of six months after the effective date of this final rule. After the 6-month period expires, this tolerance will be reduced or revoked, as indicated in the regulatory text, and allowable residues on fruit, citrus, group 10 must conform to the tolerance for subgroups 10-10A and 10-10B.

This reduction in tolerance level is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance level is supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of zeta-cypermethrin in or on the following commodities: Basil, dried leaves at 40 ppm; Basil, fresh leaves at 7 ppm; Bean, adzuki, dry seed at 0.05 ppm; Bean, American potato, dry seed at 0.05 ppm; Bean, asparagus, dry seed at 0.05 ppm; Bean, asparagus, edible podded at 0.7 ppm; Bean, black, dry seed at 0.05 ppm; Bean, broad, dry seed at 0.05 ppm; Bean, broad, succulent shelled at 0.1 ppm; Bean,

catjang, edible podded at 0.7 ppm; Bean, catjang, dry seed at 0.05 ppm; Bean, catjang, succulent shelled at 0.1 ppm; Bean, cranberry, dry seed at 0.05 ppm; Bean, dry, dry seed at 0.05 ppm; Bean, field, dry seed at 0.05 ppm; Bean, French, dry seed at 0.05 ppm; Bean, French, edible podded at 0.7 ppm; Bean, garden, dry seed at 0.05 ppm; Bean, garden, edible podded at 0.7 ppm; Bean, goa, dry seed at 0.05 ppm; Bean, goa, edible podded at 0.7 ppm; Bean, goa, succulent shelled at 0.1 ppm; Bean, great northern, dry seed at 0.05 ppm; Bean, green, dry seed at 0.05 ppm; Bean, green, edible podded at 0.7 ppm; Bean, guar, dry seed at 0.05 ppm; Bean, guar, edible podded at 0.7 ppm; Bean, kidney, dry seed at 0.05 ppm; Bean, kidney, edible podded at 0.7 ppm; Bean, lablab, dry seed 0.05 ppm; Bean, lablab, edible podded 0.7 ppm; Bean, lablab, succulent shelled at 0.1 ppm; Bean, lima, dry seed at 0.05 ppm; Bean, lima, succulent shelled at 0.1 ppm; Bean, morama, dry seed at 0.05 ppm; Bean, moth, dry seed at 0.05 ppm; Bean, moth, edible podded at 0.7 ppm; Bean, moth, succulent shelled at 0.1 ppm; Bean, mung, dry seed at 0.05 ppm; Bean, mung, edible podded at 0.7 ppm; Bean, navy, dry seed at 0.05 ppm; Bean, navy, edible podded at 0.7 ppm; Bean, pink, dry seed at 0.05 ppm; Bean, pinto, dry seed at 0.05 ppm; Bean, red, dry seed at 0.05 ppm; Bean, rice, dry seed at 0.05 ppm; Bean, rice, edible podded at 0.7 ppm; Bean, scarlet runner, dry seed at 0.05 ppm; Bean, scarlet runner, edible podded at 0.7 ppm; Bean, scarlet runner, succulent shelled at 0.1 ppm; Bean, snap, edible podded at 0.7 ppm; Bean, sword, dry seed at 0.05 ppm; Bean, sword, edible podded at 0.7 ppm; Bean, tepary, dry seed at 0.05 ppm; Bean, urd, dry seed at 0.05 ppm; Bean, urd, edible podded at 0.7 ppm; Bean, wax, edible podded at 0.7 ppm; Bean, wax, succulent shelled at 0.1 ppm; Bean, yardlong, dry seed at 0.05 ppm; Bean, yardlong, edible podded at 0.7 ppm; Bean, yellow, dry seed at 0.05 ppm; *Brassica*, leafy greens, subgroup 4-16B at 14 ppm; Bushberry subgroup 13-07B at 0.8 ppm; Caneberry subgroup 13-07A at 0.8 ppm; Celtuce at 10 ppm; Chickpea, dry seed at 0.05 ppm; Chickpea, edible podded at 0.7 ppm; Chickpea, succulent shelled at 0.1 ppm; Cottonseed subgroup 20C at 0.5 ppm; Cowpea, dry seed at 0.05 ppm; Cowpea, edible podded at 0.7 ppm; Cowpea, succulent shelled at 0.1 ppm; Fennel, Florence, fresh leaves and stalk at 10 ppm; Fruit,

pome, group 11-10 at 2 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2 ppm; Fruit, stone, group 12-12 at 2 ppm; Gram, horse, dry seed at 0.05 ppm; Grapefruit subgroup 10-10C at 0.5 ppm; Grass pea, dry seed at 0.05 ppm; Grass pea, edible podded at 0.7 ppm; Jackbean, dry seed at 0.05 ppm; Jackbean, edible podded at 0.7 ppm; Jackbean, succulent shelled at 0.1 ppm; Kohlrabi at 2 ppm; Leaf petiole vegetable subgroup 22B at 10 ppm; Leafy greens subgroup 4-16A at 10 ppm; Lemon/Lime subgroup 10-10B at 0.3 ppm; Lentil, dry seed at 0.05 ppm; Lentil, edible podded at 0.7 ppm; Lentil, succulent shelled at 0.1 ppm; Longbean, Chinese, dry seed at 0.05 ppm; Longbean, Chinese, edible podded at 0.7 ppm; Lupin, Andean, dry seed at 0.05 ppm; Lupin, Andean, succulent shelled at 0.1 ppm; Lupin, blue, dry seed at 0.05 ppm; Lupin, blue, succulent shelled at 0.1 ppm; Lupin, grain, dry seed at 0.05 ppm; Lupin, grain, succulent shelled at 0.1 ppm; Lupin, sweet white, dry seed at 0.05 ppm; Lupin, sweet white, succulent shelled at 0.1 ppm; Lupin, sweet, dry seed at 0.05 ppm; Lupin, sweet, succulent shelled at 0.1 ppm; Lupin, white, dry seed at 0.05 ppm; Lupin, white, succulent shelled at 0.1 ppm; Lupin, yellow, dry seed at 0.05 ppm; Lupin, yellow, succulent shelled at 0.1 ppm; Nut, tree, group 14-12 at 0.05 ppm; Onion, bulb, subgroup 3-07A at 0.1 ppm; Onion, green, subgroup 3-07B at 3 ppm; Orange subgroup 10-10A at 0.3 ppm; Pea, blackeyed, dry seed at 0.05 ppm; Pea, blackeyed, succulent shelled at 0.1 ppm; Pea, crowder, dry seed at 0.05 ppm; Pea, crowder, succulent shelled at 0.1 ppm; Pea, dry, dry seed at 0.05 ppm; Pea, dwarf, edible podded at 0.7 ppm; Pea, English, succulent shelled at 0.1 ppm; Pea, field, dry seed at 0.05 ppm; Pea, garden, dry seed at 0.05 ppm; Pea, garden, succulent shelled at 0.1 ppm; Pea, green, dry seed at 0.05 ppm; Pea, green, edible podded at 0.7 ppm; Pea, green, succulent shelled at 0.1 ppm; Pea, pigeon, dry seed at 0.05 ppm; Pea, pigeon, edible podded at 0.7 ppm; Pea, pigeon, succulent shelled at 0.1 ppm; Pea, snap, edible podded at 0.7 ppm; Pea, snow, edible podded at 0.7 ppm; Pea, southern, dry seed at 0.05 ppm; Pea, southern, succulent shelled at 0.1 ppm; Pea, sugar snap, edible podded at 0.7 ppm; Pea, winged, dry seed at 0.05 ppm; Pea, winged, edible podded at 0.7 ppm; Quinoa, grain at 3 ppm; Quinoa, hay at 6 ppm; Quinoa, straw at 20 ppm; Rapeseed

subgroup 20A at 0.2 ppm; Soybean, vegetable, dry seed at 0.05 ppm; Soybean, vegetable, edible podded at 0.7 ppm; Soybean, vegetable, succulent shelled at 0.1 ppm; Sunflower subgroup 20B at 0.2 ppm; Teff, forage 3 ppm; Teff, grain at 0.3 ppm; Teff, hay at 6 ppm; Teff, straw at 7 ppm; Vegetable, brassica, head and stem, group 5-16 at 2 ppm; Vegetable, fruiting, group 8-10 at 0.2 ppm; Velvetbean, dry seed at 0.05 ppm; Velvetbean, edible podded at 0.7 ppm; Velvetbean, succulent shelled at 0.1 ppm; and Yam bean, African, dry seed at 0.05 ppm.

Tolerances are also removed for the following commodities due to establishment of tolerances for the above commodities: Berry group 13 at 0.8 ppm; Borage, seed at 0.2 ppm; *Brassica*, head and stem, subgroup 5A at 2.00 ppm; *Brassica*, leafy greens, subgroup 5B at 14.00 ppm; Cabbage at 2.00 ppm; Castor oil plant, seed at 0.2 ppm; Chinese tallowtree, seed at 0.2 ppm; Cilantro, leaves at 10 ppm; Cotton, undelinted seed at 0.5 ppm; Crambe, seed at 0.2 ppm; Cuphea, seed at 0.2 ppm; Echium, seed at 0.2 ppm; Euphorbia, seed at 0.2 ppm; Evening primrose, seed at 0.2 ppm; Flax, seed at 0.2 ppm; Fruit, citrus, group 10 at 0.35 ppm; Fruit, pome, group 11 at 2 ppm; Fruit, stone, group 12 at 1 ppm; Gold of pleasure, seed at 0.2 ppm; Grape at 2 ppm; Hare's-ear mustard, seed at 0.2 ppm; Jojoba, seed at 0.2 ppm; Lesquerella, seed at 0.2 ppm; Lunaria, seed at 0.2 ppm; Meadowfoam, seed at 0.2 ppm; Milkweed, seed at 0.2 ppm; Mustard, seed at 0.2 ppm; Niger seed, seed at 0.2 ppm; Nut, tree, group 14 at 0.05 ppm; Oil radish, seed at 0.2 ppm; Okra at 0.2 ppm; Onion, bulb at 0.10 ppm; Onion, green at 3.00 ppm; Pea and bean, dried shelled, except soybean subgroup 6C at 0.05 ppm; Pea and bean, succulent shelled, subgroup 6B at 0.1 ppm; Pecan at 0.05 ppm; Pistachio at 0.05 ppm; Poppy, seed at 0.2 ppm; Rapeseed at 0.2 ppm; Rose hip, seed at 0.2 ppm; Safflower, seed at 0.2 ppm; Sesame, seed at 0.2 ppm; Stokes aster, seed at 0.2 ppm; Sunflower, seed at 0.2 ppm; Sweet rocket, seed at 0.2 ppm; Tallowwood, seed at 0.2 ppm; Tea oil plant, seed at 0.2 ppm; Turnip, greens at 14 ppm; Vegetable, fruiting, group 8 at 0.2 ppm; Vegetable, leafy, except brassica, group 4 at 10.00 ppm; Vegetable, legume, edible podded, subgroup 6A at 0.5 ppm; and Vernonia, seed at 0.2 ppm.

In addition, EPA is removing language from paragraph (a)(3) for tolerances that have

expired. The tolerances for residues of alpha-cypermethrin on “Fruit, citrus, group 10-10” at 10 ppm and “Hog, fat” at 1.0 ppm expired on December 5, 2018, as indicated by the footnote associated with those entries in the table in paragraph (a)(3). EPA is removing those expired tolerances as part of this rule as a housekeeping measure.

VI. Statutory and Executive Order Reviews

This action establishes and modifies tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct

effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act (CRA)

Pursuant to the CRA (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 22, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.418:

a. Amend paragraph (a)(2) by revising the table; and

b. Amend the table in paragraph (a)(3) by:

i. Adding the heading “Table 3 to Paragraph (a)(3)”;

ii. Removing the entries “Fruit, citrus, group 10-10¹” and “Hog, fat¹”; and

iii. Removing the corresponding footnote 1.

The additions and revisions read as follows:

§ 180.418 Cypermethrin and isomers alpha-cypermethrin and zeta-cypermethrin; tolerances for residues.

* * * * *

(a)(2) * * *

Table 2 to Paragraph (a)(2)

Commodity	Parts per million
Alfalfa, forage	15
Alfalfa, hay	30
Alfalfa, seed	0.50
Almond, hulls	6
Animal feed, nongrass, group 18, forage	8
Animal feed, nongrass, group 18, hay	40
Artichoke, globe	0.60
Avocado	0.50
Barley, grain	3.0
Barley, hay	6.0
Barley, straw	20.0
Basil, dried leaves	40
Basil, fresh leaves	7
Bean, adzuki, dry seed	0.05

Bean, American potato, dry seed	0.05
Bean, asparagus, dry seed	0.05
Bean, asparagus, edible podded	0.7
Bean, black, dry seed	0.05
Bean, broad, dry seed	0.05
Bean, broad, succulent shelled	0.1
Bean, catjang, dry seed	0.05
Bean, catjang, edible podded	0.7
Bean, catjang, succulent shelled	0.1
Bean, cranberry, dry seed	0.05
Bean, dry, dry seed	0.05
Bean, field, dry seed	0.05
Bean, French, dry seed	0.05
Bean, French, edible podded	0.7
Bean, garden, dry seed	0.05
Bean, garden, edible podded	0.7
Bean, goa, dry seed	0.05
Bean, goa, edible podded	0.7
Bean, goa, succulent shelled	0.1
Bean, great northern, dry seed	0.05
Bean, green, dry seed	0.05
Bean, green, edible podded	0.7
Bean, guar, dry seed	0.05
Bean, guar, edible podded	0.7
Bean, kidney, dry seed	0.05
Bean, kidney, edible podded	0.7
Bean, lablab, dry seed	0.05
Bean, lablab, edible podded	0.7
Bean, lablab, succulent shelled	0.1
Bean, lima, dry seed	0.05
Bean, lima, succulent shelled	0.1
Bean, morama, dry seed	0.05
Bean, moth, dry seed	0.05
Bean, moth, edible podded	0.7
Bean, moth, succulent shelled	0.1
Bean, mung, dry seed	0.05
Bean, mung, edible podded	0.7
Bean, navy, dry seed	0.05
Bean, navy, edible podded	0.7
Bean, pink, dry seed	0.05
Bean, pinto, dry seed	0.05
Bean, red, dry seed	0.05
Bean, rice, dry seed	0.05
Bean, rice, edible podded	0.7
Bean, scarlet runner, dry seed	0.05
Bean, scarlet runner, edible podded	0.7
Bean, scarlet runner, succulent shelled	0.1
Bean, snap, edible podded	0.7
Bean, sword, dry seed	0.05
Bean, sword, edible podded	0.7

Bean, tepary, dry seed	0.05
Bean, urd, dry seed	0.05
Bean, urd, edible podded	0.7
Bean, wax, edible podded	0.7
Bean, wax, succulent shelled	0.1
Bean, yardlong, dry seed	0.05
Bean, yardlong, edible podded	0.7
Bean, yellow, dry seed	0.05
Beet, sugar, roots	0.05
Beet, sugar, tops	0.20
Brassica, leafy greens, subgroup 4-16B	14
Buckwheat, grain	3.0
Buckwheat, hay	6.0
Buckwheat, straw	20.0
Bushberry subgroup 13-07B	0.8
Caneberry subgroup 13-07A	0.8
Canistel	0.50
Castor oil plant, refined oil	0.4
Cattle, fat	1.00
Cattle, meat	0.2
Cattle, meat byproducts	0.05
Celtuce	10
Chickpea, dry seed	0.05
Chickpea, edible podded	0.7
Chickpea, succulent shelled	0.1
Chinese tallowtree, refined oil	0.4
Citrus, dried pulp	1.8
Citrus, oil	4.0
Corn, field, forage	9.0
Corn, field, grain	0.05
Corn, field, stover	30
Corn, pop, grain	0.05
Corn, pop, stover	30
Corn, sweet, forage	15.00
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	15.00
Cottonseed subgroup 20C	0.5
Cowpea, dry seed	0.05
Cowpea, edible podded	0.7
Cowpea, succulent shelled	0.1
Egg	0.05
Euphorbia, refined oil	0.4
Evening primrose, refined oil	0.4
Fennel, Florence, fresh leaves and stalk	10
Food commodities/feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments	0.05
Fruit, citrus, group 10 ¹	0.35
Fruit, pome, group 11-10	2
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	2

Fruit, stone, group 12-12	2
Goat, fat	1.00
Goat, meat	0.2
Goat, meat byproducts	0.05
Grain, aspirated fractions	10.0
Gram, horse, dry seed	0.05
Grapefruit subgroup 10-10C	0.5
Grass, forage, fodder, and hay, group 17, forage	10
Grass, forage, fodder and hay, group 17, hay	35
Grass pea, dry seed	0.05
Grass pea, edible podded	0.7
Hog, fat	0.1
Hog, meat	0.05
Horse, fat	1.00
Horse, meat	0.2
Horse, meat byproducts	0.05
Jackbean, dry seed	0.05
Jackbean, edible podded	0.7
Jackbean, succulent shelled	0.1
Jajoba, refined oil	0.4
Kohlrabi	2
Leaf petiole vegetable subgroup 22B	10
Leafy greens subgroup 4-16A	10
Lemon/Lime subgroup 10-10B	0.3
Lentil, dry seed	0.05
Lentil, edible podded	0.7
Lentil, succulent shelled	0.1
Longbean, Chinese, dry seed	0.05
Longbean, Chinese, edible podded	0.7
Lupin, Andean, dry seed	0.05
Lupin, Andean, succulent shelled	0.1
Lupin, blue, dry seed	0.05
Lupin, blue, succulent shelled	0.1
Lupin, grain, dry seed	0.05
Lupin, grain, succulent shelled	0.1
Lupin, sweet white, dry seed	0.05
Lupin, sweet white, succulent shelled	0.1
Lupin, sweet, dry seed	0.05
Lupin, sweet, succulent shelled	0.1
Lupin, white, dry seed	0.05
Lupin, white, succulent shelled	0.1
Lupin, yellow, dry seed	0.05
Lupin, yellow, succulent shelled	0.1
Mango	0.70
Milk, fat (reflecting 0.10 in whole milk)	2.50
Niger seed, refined oil	0.4
Nut, tree, group 14-12	0.05
Oat, grain	3.0
Oat, hay	6.0
Oat, straw	20.0

Onion, bulb, subgroup 3-07A	0.1
Onion, green, subgroup 3-07B	3
Orange subgroup 10-10A	0.3
Papaya	0.50
Pea, blackeyed, dry seed	0.05
Pea, blackeyed, succulent shelled	0.1
Pea, crowder, dry seed	0.05
Pea, crowder, succulent shelled	0.1
Pea, dry, dry seed	0.05
Pea, dwarf, edible podded	0.7
Pea, English, succulent shelled	0.1
Pea, field, dry seed	0.05
Pea, garden, dry seed	0.05
Pea, garden, succulent shelled	0.1
Pea, green, dry seed	0.05
Pea, green, edible podded	0.7
Pea, green, succulent shelled	0.1
Pea, pigeon, dry seed	0.05
Pea, pigeon, edible podded	0.7
Pea, pigeon, succulent shelled	0.1
Pea, snap, edible podded	0.7
Pea, snow, edible podded	0.7
Pea, southern, dry seed	0.05
Pea, southern, succulent shelled	0.1
Pea, sugar snap, edible podded	0.7
Pea, winged, dry seed	0.05
Pea, winged, edible podded	0.7
Peanut	0.05
Poultry, fat	0.05
Poultry, meat	0.05
Quinoa, grain	3
Quinoa, hay	6
Quinoa, straw	20
Rapeseed subgroup 20A	0.2
Rice, grain	1.50
Rice, hulls	6.00
Rice, wild, grain	1.5
Rose hip, refined oil	0.4
Rye, grain	3.0
Rye, hay	6.0
Rye, straw	20.0
Sapodilla	0.50
Sapote, black	0.50
Sapote, mamey	0.50
Sheep, fat	1.00
Sheep, meat	0.2
Sheep, meat byproducts	0.05
Sorghum, grain, forage	0.1
Sorghum, grain, grain	0.5
Sorghum, grain, stover	5.0

Soybean, seed	0.05
Soybean, vegetable, dry seed	0.05
Soybean, vegetable, edible podded	0.7
Soybean, vegetable, succulent shelled	0.1
Star apple	0.50
Stokes aster, refined oil	0.4
Sugarcane, cane	0.60
Sunflower subgroup 20B	0.2
Sunflower, refined oil	0.5
Tallowwood, refined oil	0.4
Tea oil plant, refined oil	0.4
Teff, forage	3
Teff, grain	0.3
Teff, hay	6
Teff, straw	7
Vegetable, brassica, head and stem, group 5-16	2
Vegetable, cucurbit, group 9	0.2
Vegetable, fruiting, group 8-10	0.2
Vegetable, root and tuber, group 1, except sugar beet	0.1
Velvetbean, dry seed	0.05
Velvetbean, edible podded	0.7
Velvetbean, succulent shelled	0.1
Vernonia, refined oil	0.4
Wheat, forage	3.0
Wheat, grain	0.2
Wheat, hay	6.0
Wheat, straw	7.0
Yam bean, African, dry seed	0.05

¹ This tolerance expires on February 4, 2022.

(a)(3) * * *

Table 3 to Paragraph (a)(3)

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